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10/762,207	01/21/2004	Mark Nadel	C0989.70037US00	2512
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			EXAMINER	
			SIMS, JASON M	
			ART UNIT	PAPER NUMBER
			1631	
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			12/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/762,207

Applicant(s)

NADEL ET AL.

Examiner

Jason M. Sims

Art Unit

1631

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 66-68, 71-73, 88-99, and 134 is/are pending in the application.
- 4a) Of the above claim(s) 69-70, 74-87, and 100-133 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 66-68, 71-73, 88-99 and 134 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's arguments, filed 9/12/2007, have been fully considered but they are not deemed to be persuasive. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Applicants have amended their claims, filed 9/12/2007, and therefore rejections newly made in the instant office action have been necessitated by amendment.

Claims 69-70, 74-87, and 100-133 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventive group, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/2/2006.

Claims 66-68, 71-73, 88-99, and 134 are the current claims hereby under examination.

Claim Rejections - 35 USC § 112

Response to Arguments

Applicant's arguments, filed 9/12/2007, with respect to the rejection of claims under 35 USC 112 second paragraph have been fully considered and are persuasive because of applicant's amendment to the claims. Therefore the rejections have been withdrawn.

Claim Rejections - 35 USC § 101

Response to Arguments

Applicant's arguments, filed 9/12/2007, with respect to the rejection of claims under 35 USC 101 as being drawn to non-statutory subject matter have been fully considered and are persuasive because of applicant's amendment to the claims. Therefore the rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Chan (P/N 6,355,420).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

The claims are directed to a method of analyzing polymers through high resolution linear analysis. The polymer has a first and second specific markers with first and second specific labels at a separation distance; a detection zone is provided where a timing event is established and the polymer is moved through the detection zone at a velocity, whereby the first and second emissions by the first and second labels are detected and proportions of the first and second emissions are calculated and compared to determine the separation distance of the first and second markers.

Chan teaches claims 66, 88-97, and 134 at col. 7 - col. 10. Chan at col. 7 and 8 discusses the analysis of polymers by analyzing a polymer as it is moving through a nanochannel. Chan discusses at col. 8, lines 40-48, that the analysis may involve a measurement of the time elapsed between detected signals, which indicates the distance between two units or the length of the polymer. Chan further discusses at col. 8, lines 58-62, at least two units of the polymer are labeled differently so as to produce two different detectable signals. It is inherent that the detected signals of the first unit specific marker and second unit specific marker, which are detected as it passes through the detection signal, corresponds to a distance of the detection zone that has been traversed by the label of either the first or the second unit specific marker at the timing events. Chan discusses at col. 10, lines 57-64, that the polymers may be any type of polymer known in the art, such as a nucleic acid or proteins and that different labels can be used to label different linked units to produce different signals, such as a fluorophore or an electromagnetic label.

Response to arguments:

Applicant's arguments filed 9/12/2007 have been fully considered but they are not persuasive.

Applicant argues that there is no teaching or disclosure in Chan of identifying a proportion of a first emission signal that corresponds to a distance of a detection zone that has been traversed by a label of the first unit specific marker at a timing event and there is no mention of identifying a portion of the second emission signal that corresponds to a distance of the detection zone that has been traversed by the label of the second unit specific marker at the timing event.

Applicant's arguments are not found persuasive because Chan clearly teaches detecting emission signals from a first unit specific marker and a second unit specific marker at timing events as they pass through a detection zone. Therefore, it is inherent that the detected signals of the first unit specific marker and second unit specific marker, which are detected as it passes through the detection signal, corresponds to a distance of the detection zone that has been traversed by the label of either the first or the second unit specific marker at the timing events. It is not clear as to how a proportion of an emission signal that is not passing through a detection zone would be detected.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 102(e) as being anticipated by Gilmanishin et al. (P/N 6,263,286).

Gilmanishin et al. teaches claims 66-68, 71-73, 88-99, and 134 at the abstract, col. 5, lines 50-62, col. 14, lines 33-48, and col. 15, lines 30-67. Gilmanishin et al., in the

abstract, discusses determining the spatial separation of specific sites within a polymer. Gilmanishin et al. in the background discusses how polymers can be biological macromolecules such as DNA. Gilmanishin et al. at col. 5, lines 50-62, discusses using a polymer, or extended object, that is similarly labeled with at least two unit-specific markers and passes through a station where the impulses, or signals, are measured and an autocorrelation function is calculated, which reads on a timing event and analyzes the polymer by determining the separation distance between the measured impulses or signals. Therefore, it is inherent that the detected signals of the first unit specific marker and second unit specific marker, which are detected as it passes through the detection signal, corresponds to a distance of the detection zone that has been traversed by the label of either the first or the second unit specific marker at the timing events. Gilmanishin et al. at col. 14, lines 33-48, discusses the calculation of the separation distance between the two unit-specific markers. Gilmanishin et al. at col. 15, lines 30-67, discusses what the different polymers and what the different labels may be.

Response to arguments:

Applicant's arguments filed 9/12/2007 have been fully considered but they are not persuasive.

Applicant argues that there is no teaching or disclosure in Chan of identifying a proportion of a first emission signal that corresponds to a distance of a detection zone that has been traversed by a label of the first unit specific marker at a timing event and there is no mention of identifying a portion of the second emission signal that

corresponds to a distance of the detection zone that has been traversed by the label of the second unit specific marker at the timing event.

Applicant's arguments are not found persuasive because Chan clearly teaches detecting emission signals from a first unit specific marker and a second unit specific marker at timing events as they pass through a detection zone. Therefore, it is inherent that the detected signals of the first unit specific marker and second unit specific marker, which are detected as it passes through the detection signal, corresponds to a distance of the detection zone that has been traversed by the label of either the first or the second unit specific marker at the timing events. It is not clear as to how a proportion of an emission signal that is not passing through a detection zone would be detected.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double

patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would be obvious over, the reference claim(s). see, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 66 and 134 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3 of patent number 6,263,286. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are a species of the patented claims.

Response to arguments:

Applicant's arguments filed 9/12/2007 have been fully considered but they are not persuasive.

Applicant argues that as discussed with reference to Gilmanshin that Gilmanshin does not disclose identifying a proportion of a first emission signal that corresponds to a distance of a detection zone that has been traversed by a label of the first unit specific

marker at a timing event and there is no mention of identifying a portion of the second emission signal that corresponds to a distance of the detection zone that has been traversed by the label of the second unit specific marker at the timing event.

Applicant's arguments are not found persuasive for the reasons stated above in the instant office action.

Claim Rejections - 35 USC § 102(f)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(f) he did not himself invent the subject matter sought to be patented.

Claims 66-68, 71-73, 88-99, and 134 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

For the reasons discussed above, it is apparent that Gilmanishin et al. (P/N 6,263,286) contains claimed subject matter in claims that is not patentably distinct from instant claims 66 and 134. Because the inventive entity of Gilmanishin et al. (P/N 6,263,286) is different from the instant application, a rejection is appropriate under 35 U.S.C. 102(f). This rejection could be overcome by amendment of the appropriate claims so that the claims are patentably distinct, or by filing a declaration stating the inventive entity for the commonly claimed subject matter is identical.

Response to arguments:

Applicant's arguments filed 9/12/2007 have been fully considered but they are not persuasive.

Applicant argues that as discussed with reference to Gilmanshin that Gilmanshin does not disclose identifying a proportion of a first emission signal that corresponds to a distance of a detection zone that has been traversed by a label of the first unit specific marker at a timing event and there is no mention of identifying a portion of the second emission signal that corresponds to a distance of the detection zone that has been traversed by the label of the second unit specific marker at the timing event.

Applicant's arguments are not found persuasive for the reasons stated above in the instant office action.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jason Sims, whose telephone number is (571)-272-7540.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Michael Borin can be reached via telephone (571)-272-0713.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

// Jason Sims //

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

